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RESEARCH**

APPLICATION NUMBER:

75-456/458

CHEMISTRY REVIEW(S)

75456.004

1. CHEMISTRY REVIEW NO. 5
(This is an Electronic Submission)
2. ANDA # 75-456
3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories/McPherson, KS2
Attention: Jessie L. Lee, Ph.D.
1776 N. Centennial Drive
McPherson, KS 67460
4. LEGAL BASIS FOR SUBMISSION
The listed drug is Vasotec® I.V. (1.25 mg/mL) held by Merck & Co., Inc.,
NDA 19-309. Patent 4,374,829 which expired on 02/22/00 and has been extended to 8/22/00.
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
Enalaprilat Injection (Carpject)
7. NONPROPRIETARY NAME
Enalaprilat Injection (Carpject)
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:

Submission date	Submission type
FDA:	
10/13/98	RTF letter issued.
11/20/98	Accept to file.
4/19/99	NA letter issued
7/21/99	NA letter issued
Firm:	
09/04/98	Original
10/28/98	Amendment
11/23/98	Amendment
5/7/99	Amendment
8/6/99	Amendment (Response to NA letter dated 7/21/99)
12/17/99	Amendment
6/20/00	Minor amendment (This review)

10. PHARMACOLOGICAL CATEGORY
Antihypertensive agent
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

DMF number	DMF type	DMF holder	LOA(s)

13. DOSAGE FORM
injection

14. POTENCY

Strength	Strength units
1.25	mg/mL

15. CHEMICAL NAME AND STRUCTURE
C₁₈H₂₄N₂O₅·2H₂O M.W. 384.43
L-proline, 1-[N-(1-carboxy-3-phenylpropyl)-L-alanyl]-, dihydrate, (S)-
[84680-54-6]
Structure: See USP 23.

16. RECORDS AND REPORTS N/A

17. COMMENTS
ANDA 75-456 was tentatively approved on 1/24/00. Firm filed a Minor Amendment on 6/20/00 in accordance with the 1/24/00 TA letter stating that there have been no changes in the conditions under which the product was tentatively approved. Based on this amendment ANDA 75-456 remains approvable.

18. CONCLUSIONS AND RECOMMENDATIONS
Final Approval

19. REVIEWER:
J. Fan

DATE COMPLETED:

7/5/00

cc: ANDA 75-456
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Field Copy

Endorsements:

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

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(This is an Electronic Submission)
2. ANDA # 75-458
3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories/McPherson, KS2
Attention: Jessie Y. Lee, Ph.D.
1776 N. Centennial Drive
McPherson, KS 67460
4. LEGAL BASIS FOR SUBMISSION
Innovator Product: Vasotec I.V (NDA 19-309).
Innovator Company: Merck & Co., Inc.
Patent #4,374,829 which expired on 02/22/00 has been extended to 8/22/00.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
Enalaprilat Injection (1 mL fill in 2 mL vial and 2 mL fill in 2 mL vial)
7. NONPROPRIETARY NAME
Enalaprilat Injection (Vials)
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:

Submission date	Submission type
FDA:	
10/13/98	RTF letter issued.
11/20/98	Accept to file
5/4/99	NA letter issued.
7/21/99	NA letter issued.
Firm:	
09/04/98	Original
10/28/98	Amendment
11/23/98	Amendment
5/31/99	Amendment(Response to 5/4/99 NA letter)
8/6/99	Amendment(Response to 7/21/99 NA letter)
12/17/99	Amendment
6/20/00	Minor amendment (This review)

10. PHARMACOLOGICAL CATEGORY
Antihypertensive agent
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

DMF number	DMF type	DMF holder	LOA(s)

13. DOSAGE FORM
injection

14. POTENCY

Strength	Strength units
1.25	Mg/mL, 1mL fill in 2 mL vial
1.25	Mg/mL, 2mL fill in 2 mL vial

15. CHEMICAL NAME AND STRUCTURE

Enalaprilat USP ($C_{18}H_{24}N_2O_5 \cdot 2H_2O$) is chemically designated L-Proline, 1-[N-(1-carboxy-3-phenylpropyl)-L-alanyl]-, dihydrate, (S)-.

M.W.384.43

CAS:84680-54-6

Structure: See USP 23.

16. RECORDS AND REPORTS N/A

17. COMMENTS

ANDA 75-458 was tentatively approved on 1/24/00. Firm filed a Minor Amendment on 6/20/00 in accordance with the 1/24/00 TA letter stating that there have been no changes in the conditions under which the product was tentatively approved. Based on this amendment ANDA 75-458 remains approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

Final Approval

19. REVIEWER:

J.Fan

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